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EXAMINER

GRAFFEO, MICHELLE

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 08/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/604,928

Applicant(s)

MAXWELL ET AL.

Examiner

Michelle Graffeo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-99 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-99 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

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**DETAILED ACTION*****Status of Action***

Claims 1-99 are pending and examined. The transmittal letter filed August 27, 2003 does not identify this application as being filed under 35 U.S.C. 371. Therefore, this application is considered as filed under 35 U.S.C. 11(a).

***Claim for Priority***

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence(s) of the specification or in an application data sheet by identifying the prior application by application number (37 CFR 1.78(a)(2) and (a)(5)). If the prior application is a non-provisional application, the specific reference must also include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number. The first line of the Specification does not claim priority to the provision application or PCT/US03/26700.

***Claim interpretation***

Claim 41 is not clear in that it does not appear to use the closed language of a true Markush group. Examiner suggests that the last line of claim 41 was intended to be written as "-lated lecithin or combinations thereof" and shall interpret the claim as if written thusly.

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Claims 3-8, 17-20, 30-31, 35-36, 43-45 and 47-49 are not clear to the extent that the edible film is not necessarily described as comprising components but yet the components comprise the edible film. Claim 3 is exemplary and recites a composition "wherein the maltodextrin comprises about 5 wt% to about 60 wt% of the edible film.". These claims have been interpreted in this Action to mean that the edible film comprises maltodextrin for example, and the maltodextrin is present in the film in an amount of from 5 weight percent to about 60 weight percent.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-8, 15, 17-20, 30-31, 35-36, 42-61, and 71-88 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3-8, 17-20, 30-31, 35-36, 43-45, 47-49, 59-61, 63-67 and 72-75 recite "wt.", the meaning of which is subject to interpretation. Examiner suggests that Applicant recite the term "weight" where applicable.

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Claim 15, which depends from claim 14 recites the limitation "wherein the silicate comprises" in the first line of the claim. There is insufficient antecedent basis for this limitation in claim 14 since claim 14 does not recite the limitation "silicate".

Claims 42-61 and 71-88 are incomplete for omitting essential steps in the method claims. A method claim needs at least one step. See MPEP § 2172.01. None of the above claims recite a method step subsequent to the claim preamble of "applying a Pullulan-free edible film to the oral cavity, wherein the edible film comprises:" for example, to bring about the result recited in the preamble.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor

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and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-19, 21-22, 24, 27-44, 46-63, 65-68, 70-77, 80-81 and 83-99 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 4,971,806 to Cherukuri et al. in view of US Patent Application No. 2003/0224090 to Pearce et al. and US Patent No. 5,149,521 to Hirose et al.

Cherukuri et al. teach a chewing gum composition and methods of making same comprising:

- flavor oils and extracts derived from plants (see col 6 lines 59-64) present in an amount from 0.05-3.0% (see col 7 lines 44-45),
- up to about 90% maltodextrin (see col 5 lines 35-40),
- up to about 30% fillers (see col 5 lines 26-31 and col 4 lines 57-59) such as wood (see col 4 line 35), calcium carbonate, magnesium silicate, tricalcium phosphate and dicalcium phosphate (see col 4 lines 64-66),
- hydrocolloids such as alginates (of which one skilled in the art would find sodium and calcium to be obvious species), starch, pectin, gum arabic (see col 8 lines 15-21) wherein the starch pectin and gum arabic can be present in amounts of 0.1 to 12% (see col 8 line 45) and carrageenan (see col 5 line 22),

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- a medicament (see col 9 lines 55-end) such as aspirin, fluorides and calcium carbonate (see col 10 Lines 1-6), food acids such as citric, adipic and tartaric acid (see col 5 line 25) and antacids (col 10 line 2),
- softening agents (see col 5 line 15) such as propylene glycol present in amounts up to about 30% (see col 4 lines 45-63),
- an effective amount of a colorant (see col 5 line 3),
- flavoring agents (see col 6 line 59) such as oils (spearmint) and synthetic flavoring oils (see col 6 lines 65-end) such as citrus oil (see col 7 line 3) or menthol (see col 7 line 8) present in an amount of from 0.05 to 3% (see col 7 lines 38-45),
- emulsifiers such as lecithin (see col 5 line 20), and,
- high intensity sweeteners such as monellin and glycyrrhizin (see col 5 line 56).

Cherukuri et al. do not recited an edible film per se.

Pearce et al. teach snacks, hard candy, and chewing gum (see paragraph 3) made of orally soluble edible films comprising fillers, (see paragraph 41), hydrocolloid film-forming agents such as gums (see paragraph 28) seaweed and alginates (see paragraph 32) present in an amount from 10-90% (see paragraph 34), flavoring (see paragraph 57) wherein the flavors are present in amounts of from 0.1 to 30% (see paragraph 64), color (see paragraph 133) and oils derived from plants and fruits (see paragraph 63) wherein the moisture content is between 1-5% (see paragraph 91). The Pearce et al. references also teaches a

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method wherein the edible film encapsulates other materials or such as in a pouch or envelop or can be directly coating on pills (see col 121).

Cherukuri et al. do not recited a chewing gum comprising a pyrophosphate or polyphosphate. Nor does Cherukuri et al. recited the inclusion of cardamom specifically.

Hirose et al. teach a composition for the oral cavity comprising an easily breakable granule, menthol, a flavoring component such as cardamom (see col 1 lines 4-13) present in an amount of from 0.1 to 10% (see col 5 line 30), a water-insoluble material such as a pyrophosphate (see col 2 line 54) and a pharmaceutical agent (see col 2 lines 47-48).

Cherukuri et al. do not teach per se a method of delivering a certain amount of cardamom to the oral cavity. Nonetheless, one of ordinary skill in the art would find it obvious to routinely optimize the amount of cardamom that is added and subsequently released into the oral cavity. Cherukuri et al. expressly suggest that the amount of flavoring "employed is normally a matter of preference subject to such factors as flavor type, individual flavor, gum base and strength desired. Thus, the amount may be varied in order to obtain the result desired in the final product. Such variations are within the capabilities of those skilled in the art without the need for undue experimentation." (see col 7 lines 38-44).

Cherukuri et al. do not teach a method for reducing the number or activity of bacterial in the oral cavity per se. Nonetheless, Cherukuri et al. described a composition comprising the same ingredients as those in the instant claims,

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wherefore; the composition must have the same functional properties.

Therefore, absent evidence to the contrary, use of the composition described in Cherukuri et al. necessarily reduces the number or activity of bacteria in the oral cavity.

One of ordinary skill in the art would have been motivated to combine Cherukuri et al. with Pearce et al. and Hirose et al. and as combined would make obvious the invention as claimed above. All references are directed to edible and oral compositions such as snacks and chewing gum and contain many of the same traditional ingredients such as sweeteners, humectants such as sorbitol, food acids and flavorants, all of which are well known in the art. Additionally, both Cherukuri et al. and Pearce et al. teach the use of flavor oils and extracts derived from plants (see col 6 lines 64-65 and paragraph 63 respectively). Thus, one of ordinary skill in the art would have expected success in making a composition comprising cardamom which is extracted from a number of species of plants in the ginger family. Moreover, one skilled in the art would have found it obvious to optimizing the amount of cardamom as needed to meet any desired product specifications, for example those specifications in claims 20, 45 and 64 which require 25% cardamom, as a result of the suggestion in Pearce et al. in paragraph 64 which reads "The amount of flavoring employed is normally a matter of preference subject to such factors as flavor type, individual flavor, and strength desired. Thus, the amount may be varied in order to obtain the result desired in the final prouduct.". Thus, the claimed invention was within the

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ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

Claims 20, 45 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 4,971,806 to Cherukuri et al. in view of US Patent Application No. 2003/0224090 to Pearce et al. and US Patent No. 5,149,521 to Hirose et al. as applied to claims 1-19, 21-22, 24, 27-44, 46-63, 65-68, 70-77, 80-81 and 83-99 above and further in view of US Patent No. 6,500,406 to Rajaiah et al.

Cherukuri et al. do not disclose a composition with up to about 25% cardamom.

Rajaiah et al. disclose a denture care composition comprising from 0.001-90% of an active agent (see col 5 lines 6-8) such as anti-microbial agents (see col 6 lines 64-end) and specifically recite essential oils (see col 7 line 21) of which cardamom is one.

One of ordinary skill in the art would have been motivated to combine Cherukuri et al. with Pearce et al., Hirose et al. and Rajaiah et al. and as combined would make obvious the invention as claimed above because all references are directed to edible and oral compositions such as snacks and chewing gum that improve oral hygiene and contain many of the same traditional ingredients such as sweeteners, fluorides, humectants such as sorbitol, food acids and flavorants, all of which are well known in the art. Given that each reference includes plant oils and that Rajaiah et al. specifically include the

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essential oils as a medicament, one skilled in the art would find it obvious, given the same set of ingredients to make both a film and a gum as described above by optimizing the amount of cardamom as needed to meet any desired product specifications. Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 4,971,806 to Cherukuri et al. in view of US Patent Application No. 2003/0224090 to Pearce et al. and US Patent No. 5,149,521 to Hirose et al. as applied to claims 1-19, 21-22, 24, 27-44, 46-63, 65-68, 70-77, 80-81 and 83-99 above and further in view of US Patent No. 1,056,212 to Puetzer et al.

Cherukuri et al. do not disclose a composition comprising a medicament containing urea with a particular example but nonetheless teach (col 10 line 2) inclusion of antacids in the composition.

Puetzer et al. teaches an antacid containing urea (see first page lines 27-28).

Here, one of ordinary skill in the art would have been motivated combine Cherukuri et al. and Puetzer et al. and include a medicament, specifically a pH control agent, comprising urea in the claimed composition. As noted above, Cherukuri et al. teaches the inclusion of a pH control agent, an antacid. Puetzer et al. teach that antacids have urea. Therefore, one of ordinary skill in the art would expect success in combining the antacid of Cherukuri et al. with the

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particular characteristics of Puetzer et al. to arrive at a pH control agent comprising urea. Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

Claims 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 4,971,806 to Cherukuri et al. in view of US Patent Application No. 2003/0224090 to Pearce et al. and US Patent No. 5,149,521 to Hirose et al. as applied to claims 1-19, 21-22, 24, 27-44, 46-63, 65-68, 70-77, 80-81 and 83-99 above, and further in view of US Patent No. 5,437,902 to Andersen et al.

Cherukuri et al. do not disclose a composition comprising a medicament comprising zinc gluconate or triclosan for example. Andersen et al. teach a chewing gum comprising triclosan and zinc gluconate (see col 9 lines 29 and 39).

One of ordinary skill in the art would have been motivated to combine Andersen et al. with Cherukuri et al. and Pearce et al. All references are directed to chewing gums and the like containing traditional ingredients. Moreover Cherukuri et al. teach that medicaments can be added to the composition and teach that the list provided is non-limiting (see col 9 lines 55-end and continuing in col 10 lines 1-6). One of skill in the art would find it obvious to combine the two chewing gum references and include the medicaments in Andersen et al. into the invention of Cherukuri et al. Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

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Claim 69 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 4,971,806 to Cherukuri et al. in view of US Patent Application No. 2003/0224090 to Pearce et al. and US Patent No. 5,149,521 to Hirose et al. as applied to claims 1-19, 21-22, 24, 27-44, 46-63, 65-68, 70-77, 80-81 and 83-99 above, and further in view of WO 99/18940 to Bush Boake Allen Inc.

While Cherukuri et al. do not teach heating the aqueous solution to a temperature of 40-60°C; the WO 99/18940 reference teaches a process wherein the aqueous mixture was heated preferably from about 40-70°C.

One of ordinary skill in the art would have been motivated to combine WO 99/18940 with Cherukuri et al. and Pearce et al. WO 99/18940 is directed to an oral vehicle such as chewing gum comprising the traditional ingredients such as fillers (see page 15 lines 20-26), hydrocolloids (see page 17 line 32), maltodextrin and sweeteners (see page 17 line 32 as well). One skilled in the art would be motivated to use the process of making the oral vehicle as well as any variations of ingredients as described in WO 99/18940 because the ingredients are traditionally used in the art. Moreover, one skilled in the art would expect success using the method described in WO 99/18940 particularly since the ingredients are the same. Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

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Claims 78-79 and 82 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 4,971,806 to Cherukuri et al. in view of US Patent Application No. 2003/0224090 to Pearce et al. and US Patent No. 5,149,521 to Hirose et al. as applied to claims 1-19, 21-22, 24, 27-44, 46-63, 65-68, 70-77, 80-81 and 83-99 above and further in view of US Patent No. 4,568,560 to Schobel.

The Cherukuri et al. reference does not teach encapsulated cardamom or spray dried cardamom.

Schobel is directed to a denture cleansing composition (see col 6 Example III) and a method of spray drying (see col 2 lines 45-60) or encapsulating a flavor (see col 2 lines 61-end) such as those oils derived from plants (see col 4 lines 60-61).

One of ordinary skill in the art would have been motivated to combine Cherukuri et al. with Pearce et al., Hirose et al. and Schobel and as combined would make obvious the invention as claimed above. All references are directed to edible and oral compositions such as snacks and chewing gum and contain many of the same traditional ingredients such as sweeteners, humectants such as sorbitol, food acids and flavorants, all of which are well known in the art. Additionally, both Cherukuri et al., Pearce et al. and Hirose et al. teach the use of flavor oils and extracts derived from plants (see col 6 lines 64-65 and paragraph 63 respectively). Thus, one of ordinary skill in the art would expect success using cardamom, which is extracted from a number of species of plants in the ginger family, in the encapsulating process taught in Schobel which also teaches

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the process with oils of plant extracts. Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-99 are provisionally rejected under the judicially created doctrine of double patenting over claims 1-99 of copending Application No. 10/604923.

This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: the '923 Application claims a pullulan free edible film comprising a film forming agent

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and an effective amount of an antimicrobial agent. The limitations of each dependent claim of the '923 are recited verbatim as those in the instant application but for the specific antimicrobial agent used. Specifically, the '923 application claims a method of using a pullulan free edible film, a method of making a pullulan free edible film and a pullulan free edible film (formed for example into a candy comprising 1-4% moisture) comprising:

- 5-60% maltodextrin,
- 10-50% hydrocolloid selected from a natural gum (such as natural seed gum, guar gum, locust gum, tara gum, gum Arabic, ghatti gum, agar gum and xanthan gum), biosynthetic gum, a natural seaweed (with carrageenan), a natural plant extrudate, a natural fiber extract, a gelatin, a biosynthetic process starch, a cellulosic material, an alginate (such as sodium or calcium), a pectin or combinations thereof,
- 5-30% filler selected from microcrystalline cellulose, a cellulose polymer (additionally comprising wood), magnesium carbonate, calcium carbonate, ground limestone, a silicate (including magnesium or aluminum), clay, talc, titanium dioxide, a calcium phosphate (comprising mono-calcium phosphate, di-calcium phosphate, or tri-calcium phosphate) and combinations thereof,
- 1-25% citral,
- a medicament comprising an oral cleansing or breath freshening compound selected from the group consisting of a pH control agent

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- (comprising urea), inorganic components for tartar or caries control (comprising phosphates or fluorides), a breath freshening agent (comprising zinc gluconate), an anti-plaque/anti-gingivitis agent (comprising chlorhexidine, CPC or triclosan), a saliva stimulating agent (comprising a food acid selected from the group consisting of citric, lactic, maleic, succinic, ascorbic, adipic, fumaric, tartaric and combinations thereof), a pharmaceutical agent, a nutraceutical agent, a vitamin, a mineral and combinations thereof,
- 0-20% a softening agent wherein the softening agent comprises a plasticizer including a compound selected from the group consisting of sorbitol, glycerin, polyethylene glycol, propylene glycol, hydrogenated starch hydrolysates, corn syrup and combinations thereof,
  - a coloring agent,
  - 0.1-20% a flavoring agent selected from the group consisting of essential oils (selected from the group consisting of citrus oil, spearmint oil, mint oil, clove oil, oil of wintergreen and combinations thereof), synthetic flavors, fruit essences, anise, flavor oils with germ killing properties (comprise menthol, eucalyptol, thymol and combinations thereof) and mixtures thereof,

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- emulsifying agent wherein the emulsifying agent comprises lecithin, (C10-C18) fatty acids, monoacyl glycerides, di-acyl glycerides, ox bile extract, polyglycerol esters, polyethylene sorbitan esters, propylene glycol, sorbitan monopalmitate, sorbitan monostearate, sorbitan tristerate, enzyme modified lecithin, hydroxylated lecithins and combinations thereof,
- a pyrophosphate or polyphosphate,
- a high intensity sweetener selected from the group consisting of, sucralose, aspartame, NPM derivatives such as neotame, salts of acesulfame, altitame, saccharin and its salts, cyclamic acid and its salts, glycyrrhizinate, dihydrochalcones, thaumatin, monellin, and combinations thereof,
- a cooling agent selected from the group consisting of menthol, ethyl p-menthane carboxamide, N,2,3-trimethyl-2-isopropyl-butanamide, menthyl glutarate FEMA 4006, menthyl succinate, menthol PG carbonate, menthol EG carbonate, menthyl lactate, menthone glyceryl ketal, menthol glyceryl ether, N-tert-butyl-p-menthane-3-carboxamide, p-menthane-3-carboxylic acid glycerol ester, methyl-2-isopropyl-bicyclo (2.2.1), heptane-2-carboxamide, menthol methyl ether and combinations thereof,

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wherein the citral is encapsulated or spray dried and further wherein the composition is formulated to deliver at least 0.005% concentration of citral to the oral cavity.

Claims 1-99 are provisionally rejected under the judicially created doctrine of double patenting over claims 1-128 of copending Application No. 10/604921. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: the '921 Application claims a pullulan free edible film comprising a film forming agent and an effective amount of an antimicrobial agent. The limitations of each dependent claim of the '921 are recited substantially verbatim as those in the instant application but for the specific antimicrobial agent used. Specifically, the '921 application claims a method of using a pullulan free edible film, a method of making a pullulan free edible film and a pullulan free edible film (formed for example into a candy comprising 1-4% moisture) comprising:

- 5-60% maltodextrin,
- 10-50% hydrocolloid selected from a natural gum (such as natural seed gum, guar gum, locust gum, tara gum, gum Arabic, ghatti gum, agar gum and xanthan gum), biosynthetic gum, a natural

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seaweed (with carrageenan), a natural plant extrudate, a natural fiber extract, a gelatin, a biosynthetic process starch, a cellulosic material, an alginate (such as sodium or calcium), a pectin or combinations thereof,

- 5-30% filler selected from microcrystalline cellulose, a cellulose polymer (additionally comprising wood), magnesium carbonate, calcium carbonate, ground limestone, a silicate (including magnesium or aluminum), clay, talc, titanium dioxide, a calcium phosphate (comprising mono-calcium phosphate, di-calcium phosphate, or tri-calcium phosphate) and combinations thereof,
- 1-25% geranoil,
- a medicament comprising an oral cleansing or breath freshening compound selected from the group consisting of a pH control agent (comprising urea), inorganic components for tartar or caries control (comprising phosphates or fluorides), a breath freshening agent (comprising zinc gluconate), an anti-plaque/anti-gingivitis agent (comprising chlorhexidine, CPC or triclosan), a saliva stimulating agent (comprising a food acid selected from the group consisting of citric, lactic, maleic, succinic, ascorbic, adipic, fumaric, tartaric and combinations thereof), a pharmaceutical agent, a nutraceutical agent, a vitamin, a mineral and combinations thereof,

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- 0-20% a softening agent wherein the softening agent comprises a plasticizer including a compound selected from the group consisting of sorbitol, glycerin, polyethylene glycol, propylene glycol, hydrogenated starch hydrolysates, corn syrup and combinations thereof,
- a coloring agent,
- 0.1-20% a flavoring agent selected from the group consisting of essential oils (selected from the group consisting of citrus oil, spearmint oil, mint oil, clove oil, oil of wintergreen and combinations thereof), synthetic flavors, fruit essences, anise, flavor oils with germ killing properties (comprise menthol, eucalyptol, thymol and combinations thereof) and mixtures thereof,
- emulsifying agent wherein the emulsifying agent comprises lecithin, (C10-C18) fatty acids, monoacyl glycerides, di-acyl glycerides, ox bile extract, polyglycerol esters, polyethylene sorbitan esters, propylene glycol, sorbitan monopalmitate, sorbitan monostearate, sorbitan tristearate, enzyme modified lecithin, hydroxylated lecithins and combinations thereof,
- a pyrophosphate or polyphosphate,
- a high intensity sweetener selected from the group consisting of, sucralose, aspartame, NAPM derivatives such as neotame, salts of

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acesulfame, altitame, saccharin and its salts, cyclamic acid and its salts, glycyrrhizinate, dihydrochalcones, thaumatin, monellin, and combinations thereof,

- a cooling agent selected from the group consisting of menthol, ethyl p-menthane carboxamide, N,2,3-trimethyl-2-isopryl-butanamide, menthyl glutarate FEMA 4006, menthyl succinate, menthol PG carbonate, menthol EG carbonate, menthyl lactate, menthone glyceryl ketal, menthol glyceryl ether, N-tert-butyl-p-menthane-3-carboxamide, p-men-thane-3-carboxylic acid glycerol ester, methyl-2-isopryl-bicyclo (2.2.1), heptane-2-carboxamide, menthol methyl ether and combinations thereof,

wherein the geranoil is encapsulated or spray dried and further wherein the composition is formulated to deliver at least 0.005% concentration of geranoil to the oral cavity.

The '921 and '923 applications recite different antimicrobial components in the composition. Nonetheless, one of ordinary skill in the art would find it obvious to substitute both the geranoil and/or the citral for the cardamom based on the teachings of Pearce et al. which in paragraph 137 states that with "various films, particularly where the film encapsulates or is layered with another material, it may be desirable to include ingredients, especially in the encapsulated or co-layered material, other than mere sweeteners and flavoring, such as a bacterial, antiseptic, antimicrobial..." Thus, one of ordinary skill in the art would make the

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obvious substitution of one antimicrobial for the other and the '921 and '923 applications obvious over the instant application.

No claim is allowed.

**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Graffeo whose telephone number is 571-272-8505. The examiner can normally be reached on 9am to 5:30pm Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

1 August 2005  
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